

Comments submitted to the SAB Subcommittee on Policies and Procedures

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The Center for Health, Environment & Justice (CHEJ) is pleased that the US EPA's Science Advisory Board (SAB) has formed the Subcommittee on Policies and Procedures to address the issues of conflicts of interest and bias that affect the integrity and balance of SAB committees. CHEJ and our constituency of grassroots community based organizations have closely followed the work of the Dioxin Reassessment Review Subcommittee (DRRS) of the SAB that reviewed the USEPA's draft reassessment report on dioxin. We have attended and provided testimony at the public meeting in November, 2000; participated in teleconference calls; attended the public peer review meeting held in July 2000; provided written comments on the DRRS review of the EPA report; and, generally, have followed the EPA's and SAB's review process for dioxin since 1994. We also attended and provided written comments at the May 15, 2001 meeting of the Executive Committee (EC) of the SAB.

In these past comments we have expressed our concern about the way that the DRRS conducted its review of the EPA's dioxin reassessment report. We remain deeply concerned about the fairness and transparency of this process. We believe that the normal objective and disinterested scientific peer review process was subverted and replaced with a highly politicized process aimed at delaying if not preventing the agency from finalizing their health assessment document and releasing it to the American people. We are troubled that the SAB would engage in such politically motivated actions.

It is our understanding that the Executive Committee of the SAB was also sufficiently concerned about the DRRS review process that Dr. William Glaze, chair of the EC, agreed to conduct an "investigative study" into the many charges and concerns raised by the public during May 15th public meeting. However, as expressed in a recent letter to Dr. Glaze, we are disappointed that five months have passed and we have heard nothing about the progress of an "investigative study" into the way the DRRS conducted its review of the agency's dioxin reassessment report.

The newly formed Subcommittee on Policies and Procedures seems appropriately organized to address these concerns. However, it is unclear if this committee plans to conduct an investigation of the DRRS review process. We would like to see this committee undertake this effort.

We feel that the current effort to respond to the concerns raised by the recent General Accounting Office (GAO) report is not sufficiently focused on the dioxin DRRS review process to address the concerns raised by CHEJ and others including a member of the DRRS panel during the

public comments at the May 15th EC meeting. CHEJ's specific concerns are described in a letter written to Dr. Glaze on June 25, 2001 (attached). We feel just as strongly now that the dioxin reassessment review process was an embarrassment to the SAB and that it has contributed substantially to the erosion of the scientific credibility of the agency. We await Dr. Glaze's response regarding how the EC plans to proceed with its "investigative study" of the DRRS review process.

There are sufficient similarities and overlap between the concerns raised by the GAO report and by the public comments at the May 15th EC meeting, that we felt we could contribute to this general review of the issues of conflicts of interest and bias affecting the integrity and balance of SAB committees. However, unless the focus of this effort is altered to specifically include the discussion of the DRRS review, then we do not feel that this process will address the concerns that we and others raised at the May 15th meeting.

The comments below are provided mostly in the context of the DRRS review process. Additional specific concerns about the conduct of the dioxin panel which are summarized below as item #6 and described in more detail in the June 25, 2001 letter to Dr. Glaze which is attached.

(1) What specific types of information about SAB panel members would be useful to you as you assess a panel for possible conflicts of interest and bias? Please provide specific, concrete suggestions if possible.

In addition to the routine assessment of direct financial investments and ownership, it's also important to evaluate the potential for bias and conflicts of interest in the context of the particular charge of a committee. The issue here is whether a potential committee member or the company or institution that they work for has received funding from an organization or company that stands to gain or take advantage of the outcome of a regulation or report. This would require obtaining information from potential SAB committee members about their past employment and about sources of funding for their work that goes directly to them and that goes to them indirectly via funding from the affected companies to the institution or company that they work for.

For example, at the November, 2000 public meeting of the SAB's DRRS, it was revealed that six members of the committee had received a combined 91 grants from industries that would be impacted by the regulation of dioxin. Currently the SAB does not see this as conflict of interest. We disagree. At a minimum, this situation indicates that there is a bias in those individuals who received these 91 grants that should be publicly disclosed.

From the beginning of the review of the dioxin report by the DRRS panel, this situation caused the panel to become polarized between those members who received funds from these companies and those who were trying to honestly provide the agency with comments that will improve the science in their report. Evidence of this split would likely be evident by looking at the break-out of how panel members voted on eight issues/statements addressed in this report.

(2) What information would be useful for you to know about EPA's panel selection decision-making process? That is, what do you need to know to determine if we've done an acceptable review of conflict of interest and bias and if we've adequately balanced a panel?

The process needs to be transparent. Who selects candidates for a committee? How are candidates selected? Based on what criteria? What areas of discipline are needed? Who decides this? Who decides whether a candidate meets the criteria? What questions regarding conflicts of interests and bias are asked BEFORE a candidate is selected? There is no transparency in the current process. When these or similar questions were posed regarding the formation of the dioxin panel, the response was consistent - the SAB staff decides. This response in isolation of a detailed explanation of how decisions are made is insufficient and inadequate. How candidates are selected and on what basis should be clearly transparent to anyone who asks. In addition, the public should have the opportunity to comment on potential candidates and to provide additional information that may not have been available or brought to the attention of those making the selection decisions.

It is also problematic that some committee members are chosen from a roster of "consultants" that are screened and pre-selected. Defining the universe of scientists who could be added to a committee in this way clearly limits the choice of candidates. This process allows SAB staff to select scientists who have not been specifically screened for the type of bias and conflict of interest described above. The selection of the dioxin panel illustrates this problem. In this case, the panel members were selected from a combination of the original SAB committee that reviewed the report in 1995 and "available" candidates from the consultants list. Truly new faces were never considered.

(3) What is your reaction to the enclosed table of proposed procedural changes that SAB staff has developed? Please bring to our attention to concerns about the specifics in this table as well as additional concerns or recommendations that merit our attention.

No comment.

(4) What other areas should concern the Policies and Procedures Subcommittee ? beyond the specific areas identified by the GAO report and/or this table? For example, to achieve our broad aim of ensuring continued integrity and accountability of board advice, should we be looking beyond committee composition to other aspects of committee operations? Should we reconsider how we recruit potential panel members, including the development of lists of qualified scientists? We would appreciate any specific recommendations on how we should proceed in each area of concern to you.

You're assuming that it's clear how you currently recruit panel members. As described above, it's not. It is clear that there are

few public interest scientists on SAB committees. And given the current state of affairs defined by the GAO report as well as the public experience of the dioxin committee, there is little to encourage or elicit participation by the public interest sector.

Also, if you only draw from an existing roster who have already been generally selected, then you severely limit the choices available to you, especially if you truly look to balance the composition of committees. The search for candidates needs to go beyond the members of a standing SAB committee or the consultant's list.

The current process used by the SAB staff to determine and evaluate committee composition is inadequate and in fact misleading. On at least several occasions Donald Barnes, staff director of the SAB, has presented a chart showing the composition or profile by affiliation of SAB membership (see chart prepared for ACC Congressional Briefing, August 21, 2001). The General categories used to generate this profile are: tribal, environmental, state, research institution, consultant, industry, and academic.

This analysis is overly simplistic. With the exception of the tribal group, these categories primarily define where a person works. It says little about the viewpoint someone who works in these groups would bring to the table. And it says virtually nothing about potential conflicts of interest or bias. Many consultants work primarily for industry as do many academics and research scientists. It's important to look beyond this simplistic view and to understand who pays the academic, the consultants and the scientists who work at research institutions. For example, in this simplistic break-out, a scientist who works for CIIT is likely to be placed in the research institution category. While this placement may be consistent with the Barnes break-out, it's not accurate - or honest - to imply that this person represents a perspective that is different than someone from industry.

The problem is that these profile categories include general groups - academic, research institution, and consultant - that have significant overlap. By using these profile categories, the SAB is not able to distinguish different viewpoints and determine how to accurately or fairly balance committee composition. For example, it's very possible to put together a committee that is stacked so that 8 or 9 of 20 committee members represent a particular point of view compared with only 1 or 2 members having an opposing viewpoint. This is what seems to happen repeatedly in SAB committees. This is why public interest scientists are reluctant to participate once they have gone through this process once.

The categories need to be reassessed to better define diversity of viewpoints. This is critical to selecting committees that are evenly balanced and avoid the bias and conflicts of interest that occurred in the dioxin panel. If a consultant, academic, or research scientist, or his/her firm/institution has received substantial funding from a company that is or will be directly affected by a rule or regulation that will result from committee deliberations, this is a conflict of interest.

Such conflicts need to be divulged and publicly acknowledged and considered a bias that needs to be balanced.

(5) Are there other model advisory committees for us to research or scholarly papers that have been written on these issues that might inform the deliberations of the committee?

I'm sure you're looking at the process and procedures used by the National Academies of Science. Simply adopting the process and procedures used by the NAS would substantially improve the current SAB process.

(6) In addition to the issues described above, the following concerns raised in the June 25, 2001 letter to EC Chair William Glaze provide additional specific examples of other problems with the SAB peer review process. This letter addresses the behavior of the Chair of the dioxin review panel and SAB staff at the May 15, 2001. The full text of the letter is attached.

1. At the SAB Executive Committee meeting, Dr. Lippmann and Mr. Rondberg assured the Executive Committee that the DRRS had "signed off" on the DRRS report and the Executive Summary. In fact, no sign off of the document was solicited or received. Dr. Lippmann and Mr. Rondberg never engaged the members of the subcommittee in a sign off process. Instead Lippmann and Rondberg assumed that the absence of a minority report was a synonym for unanimous support. If the SAB instructed its subcommittees to employ a sign off process, such as used by the National Academy of Sciences, the consensus or divergence in opinion of committee members would be not be subject to such misinterpretations of fact.

2. The SAB process is better served by having chairs that are not partisans of the extremes on the issue under review. It is clear from the May and the November public meetings that Dr. Lippmann has very strong opinions about the risks posed by dioxin. While he does not dispute the result of the agency's cancer risk estimate for dioxin derived by using its cancer risk guidelines, he simply "does not believe the result" nor that dioxins are in fact, dangerous. This opinion was also expressed by Dr. Lippmann at the DRRS meeting in 1995. Dr. Lippmann is certainly entitled, as is every American, to believe what he wants about dioxin, or any other substance, but having this opinion certainly influences his judgment and should have been considered when he was chosen to chair a committee to evaluate the health effects of dioxin.

3. The actions of Dr. Barnes added to the misinterpretations of fact and atmosphere of bias. When describing the interactions with DRRS member Dr. Richard Clapp, Dr. Barnes did not accurately report that he had discouraged Dr. Clapp's presence at the Executive Committee meeting. This clarification had to be made by Dr. Greer. Dr. Barnes' lack of candor about his conversations with Dr. Clapp aided Dr. Lippmann and Mr. Rondberg in making their case that the DRRS report was strongly supported by the Subcommittee, when in fact it was not. Dr. Barnes'

rude treatment of Dr. William Farland was also noted to be at odds with the SAB EC who wanted to continue to hear from Dr. Farland, but were not allowed to by Dr. Barnes. This behavior brings to question who in fact is running the EC meeting.

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